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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,657	02/20/2001	Ulf Landegren	LANDEGREN=1A	5356

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EXAMINER	
CHUNDURU, SURYAPRABHA	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,657	LANDEGREN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,13-15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,13-15 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on January 12, 2004 has been entered.

2. Claims 2-7, 13-15 and 17-25 are pending.

Priority

3. The instant application is filed on February 20, 2001 and claims the benefit of US provisional application No. 60/183371, filed on February 18, 2000.

Response to Arguments

4. Applicants' response to office action (Paper Nos. 20 and 22) are fully considered and found persuasive in part.

5. With regard to the rejection made in the previous office action under 35 USC 102(e) as anticipated by Landegren (USPN.6,558,928), Applicants' arguments are fully considered and found persuasive and the rejection is withdrawn herein.

6. The Declaration under 37 CFR 1.132, submitted by the Applicants is fully considered, and found persuasive and acknowledge that the patent '928 not prior art under 35 USC 102(e) and WO 99/49079 does not qualify as a prior art under 35 USC 102(a).

7. With regard to rejection made under 35 USC 103(a) Applicants' arguments are fully considered and the rejections are withdrawn herein in view of and Applicant's arguments that the primary reference ('928) is not a prior art, and new grounds of rejection.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 recites the limitation "the drug candidate molecule". There is insufficient antecedent basis for this limitation in the claim. The limitation in the instant claim 15 lacks antecedent basis because the claim 25, upon which the instant claim depends, does not support the limitation.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 3-5, 7, 22-23, are rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al. (USPN. 4,988,617).

Landegren et al. ('617) teach a method of 25, for detecting analyte(s) (target nucleic acid) in a solution (see column 20, lines 17-50, lines 67-68, column 21, lines 1-6) wherein the method comprises

(a) binding of two or more proximity probes (oligonucleotides) to a respective binding site on the analyte, (see column 3, lines 1-9, column 4, lines 12-30, column 20, lines 17-34);

(b) allowing the binding moiety to bind one or more analytes, and allowing the nucleic acids to interact with each other by base pairing if they are in close proximity to each other (see column 3, lines 5-15, column 20, lines 35-41);

(c) detecting the degree of interaction between the nucleic acids (see column 3, lines 18-20, lines 44-50).

With regard to claim 25, Landegren et al. also teach that the proximity probes are comprised of a binding moiety (biotin) and allowing binding moiety to bind to the analyte and the proximity probes interact with each other (adjacent oligonucleotide probes join each other) (see column 4, lines 34-50, column 5, lines 4-8, column 10, lines 50-62).

With regard to claim 3, 23, Landegren et al. ('617) teach that the binding moiety is selected from protein (biotin), carbohydrates, nucleic acids (see column 4, lines 39-42, column 5, lines 4-8, column 10, lines 50-67);

With regard to the claim 4, Landegren et al. ('617) teach that the analyte (s) are selected from nucleic acids (see column 4, lines 12-15);

With regard to claim 5, Landegren et al ('617) teach that the binding sites for the binding moieties of the proximity probes are situated on the same analyte (see column 10, lines 53-63);

With regard to claim 14, Landegren et al. teach that the first proximity probe comprises purified (amplified) analyte (test DNA) coupled to an oligonucleotide (see column 7, lines 25-46, column 8, lines 30-42);

With regard to claim 17 Landegren et al. also teach that the method can be used to detect infectious agents in a test substance (see column 4, lines 12-19);

With regard to claim 7, Landegren et al. also teach that the interaction of said nucleic acids coupled to binding moieties is through hybridization to a common splint template (terminal common nucleotide) and ligation of the nucleic acid ends (see column 7, lines 4-46);

With regard to claim 22, said method comprises three probes wherein the 3' and 5' of the probes comprise free nucleotides which interact with adjacent probe segment (see column 5, lines 1-25). Thus the disclosure of Landegren et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 2, 6,13,15, 18-21, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landegren et al. (USPN. 4,988,617) ('617) in view of Landegren (WO 97/00446) (00446).

Landegren et al. ('617) teach a method of 2, 6, 13,15, 18-21, and 24 for detecting analyte(s) (target nucleic acid) in a solution (see column 20, lines 17-50, lines 67-68, column 21, lines 1-6) wherein the method comprises

(a) binding of two or more proximity probes (oligonucleotides) to a respective binding site on the analyte, (see column 3, lines 1-9, column 4, lines 12-30, column 20, lines 17-34);

(b) allowing the binding moiety to bind one or more analytes, and allowing the nucleic acids to interact with each other by base pairing if they are in close proximity to each other (see column 3, lines 5-15, column 20, lines 35-41);

(c) detecting the degree of interaction between the nucleic acids (see column 3, lines 18-20, lines 44-50).

Landegren et al. also teach that the proximity probes are comprised of a binding moiety (biotin) and allowing binding moiety to bind to the analyte and the proximity probes interact with each other (adjacent oligonucleotide probes join each other by base pairing) (see column 4, lines 34-50, column 5, lines 4-8, column 10, lines 50-62). However, Landegren et al. did not teach amplification of interacted nucleic acids, antibody binding moieties directed against the Fc portion of further antibody, high-throughput screening for ligand-receptor interaction antagonists.

Landegren ('00446) teaches a method for detecting analyte(s), wherein the method comprises (i) amplification of the interacted nucleic acids and detection of amplified product (see page 4, lines 7-8, page 5, lines 36-38); binding moiety as antibodies, each bind to one or more analytes via further antibodies (two or more antibodies) (see page 1, abstract, page 3, paragraph 4, page 4, lines 1-8, 26-31). Landegren also teaches that the method comprises screening ligand or drug candidates (antigen), wherein the antigen is a biomolecule (see page 6, paragraphs 1-3); the antigen or macromolecule include human myoglobin and human growth hormone (see page 6, lines 21-24), detecting the antigen in a high-through put format (manifold support) (see page 7, lines 10-35).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method for detecting one or more analytes as taught by Landegren et al.('617) with a method using enhanced signal by amplification and antibody binding moieties, to achieve expected advantage of developing an improved method for detecting a target analyte using immunological reactants because Landegren ('00446). taught that the invention enables detection of extremely low numbers of antigenic molecules, even down to a single molecule (see page 3, paragraph 1). An ordinary practitioner would have been motivated to combine the method of Landegren et al. ('617) with the incorporation of amplified signal generating procedures as amplification and antibody binding as taught by Landegren (00446) for the expected benefit of increasing the detection signals of a target analyte.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
February 24, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER